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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,777	09/21/2001	Suzanne V. Smith	11184.00002	8748

22908 7590 03/18/2003

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EXAMINER
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HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 03/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/869,777

Applicant(s)

SMITH ET AL.

Examiner

Michael G. Hartley

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 8-23 is/are rejected.
- 7) ☒ Claim(s) 3 and 7 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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**Response to Amendment**

The preliminary amendment filed 12/11/2002 has been entered. The specification has been amended as requested.

**Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6, 15, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of claim 6, that " $R^2$  and  $R^3$  taken together with the nitrogen atom of  $NR^2R^3$  form an optionally substituted saturated or partially unsaturated ring..." is confusing because such a ring as defined herein is not within the scope of base claim 1 in the definition of  $R^2$  and  $R^3$ . Thus, the definition set forth in claim 6 for  $R^2$  and  $R^3$  contradicts the definition in base claim 1.

Claims 15, 19 and 22 provides for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

**Claim Rejections - 35 USC § 101**

Claims 15, 19 and 22 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4-6, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcuccio (WO 95/31202).

Marcuccio discloses a compound of formula 1 on page 4. In this compound variables A1-A6 are NH, N, O or S and R1 and R2 include substituted alkyl, wherein the substitution includes carboxy, amino, mercapto, etc., see page 11. The R1 and R2 groups may further be substituted with heterocyclyl groups, such as pyridyl, etc., thereby encompassing claim 6. Such substitution would yield compounds encompassed by claims rejected herein. The R1 group also includes a sugar moiety (e.g., carbohydrate) as set forth in claim 2 (however, it is noted that claim 2 does not limit the claim to those having a molecular recognition unit, but only recites what is encompassed thereby). The compounds form a complex with a metal ion, including Co, see page 4 and 19. Marcuccio teaches that the compounds may include various substitutions to provide functional groups thereon (e.g., page 28), as well as, that the various substitutions may be used to optimize the desired properties of the compounds, i.e., solubility.

While teaching compounds which include substitutions encompassing compounds as claimed, Marcuccio fails to specifically disclose (e.g., exemplify) compounds which are within the scope of those claimed.

It would have been obvious to one of ordinary skill in the art to have prepared any of the compounds taught by Marcuccio, including those having substitutions to yield compounds within the scope of those claimed, because Marcuccio teaches that the compounds may include various substitutions as equivalents and that these chemical moieties provide functional groups on the cryptate compounds, as well as, the advantage that would be gleaned from selection of the various substitutions

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taught, such as, to obtain compounds having desired properties (e.g., increased/decreased solubility, etc.).

Claims 1, 2, 4-6 and 8-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marcuccio (WO 95/31202) in view of Alvarez (US 4,741,900).

Marcuccio teaches that cryptate compounds, which encompass those claimed, are effective for chelating metals and are safe for *in vivo* use, as set forth above.

Marcuccio fails to disclose that the cryptates may include a radiometal for use as a radiopharmaceutical.

Alvarez discloses radiopharmaceutical compositions for diagnostic or therapeutic methods comprising radiometal complexes, see abstract. The radiometals include  $^{67}\text{Cu}$  as claimed, see column 3, lines 54+. The chelators include cryptates and derivatives thereof (see column 10, line 12 and claim 9) which further include a targeting moiety, e.g., an antibody, carbohydrate, etc., see column 8 and 10. The compositions include a reducing agent for stabilization, see column 13, line 1+ and pharmaceutical compositions, column 14, lines 63+.

It would have been obvious to one of ordinary skill in the art to have used the cryptate compounds disclosed by Marcuccio to form a complex with a radiometal because Marcuccio teaches that various metals may be employed and that complexes are useful for *in vivo* use, and it is known in the art that cryptate compounds may be radiolabeled to provide an effective radiopharmaceutical for both therapeutic and diagnostic use, as shown by Alvarez. One of ordinary skill in the art would have been motivated to substitute a radiometal for the metal in the cryptate compounds disclosed by Marcuccio to maximize their disclosed utility as chelating agents because it is known in the art that such cryptate compounds are effective chelates for radiometals to provide the advantage of yielding a radiopharmaceutical, as shown by Alvarez.

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***Claim Objections***

***Allowable Subject Matter***

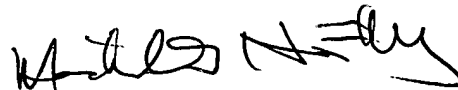
Claims 3 and 7 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest the cryptate compounds as set forth in these claims.

Claims 3 and 7 are also objected to because these claims fail to end with a period as required, thus, it is unclear where the claim ends.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose G. Dees can be reached on (703) 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

MH  
March 14, 2003